



RECOMMENDATIONS / Technical

Expert consensus: Renal denervation for the treatment of hypertension[☆]

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Abstract Catheter-based renal denervation is a new method able to disrupt renal sympathetic nerves located in the adventitia of renal arteries. A randomized clinical trial showed a decrease in blood pressure in resistant hypertensive patients. In order to guide clinicians and interventional practitioner for the use of this new approach, different French scientific societies (Hypertension, Cardiology and Radiology) decided to combine their expertise and propose an expert consensus to assess benefit/risk ratio of this technique in the field of arterial hypertension. In 2012, this expert consensus propose to limit renal denervation technique to patients with essential hypertension uncontrolled by four or more antihypertensive therapies with at least one treatment being a diuretic and spironolactone at a dose of 25 mg shown to be

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unable to control blood pressure. Measurement of office BP should be at least with SBP more than 160 mmHg and/or DBP more than 100 mmHg confirmed by ambulatory BP measurement (home or ABP measurement with SBP more than 135 mmHg and DBP more than 85 mm during daytime period). Finally, renal artery anatomy and function should allow proper intervention (i.e., two functional kidneys, absence of previous renal angioplasty). Renal denervation is a complex interventional procedure with potentially arterial complications, training is required for practitioners. Antihypertensive treatment should not be interrupted immediately after renal denervation since blood pressure lowering effect are delayed and reached maximum effect after 3 months. Monitoring of blood pressure, renal function and anatomy of renal arteries is required 12 months and 36 months after procedure. The expert consensus requires the inclusion of patients experiencing this procedure in a observational study with record form and follow-up.

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Renal denervation via the endovascular route is a new method for which a randomised clinical study showed a decrease in blood pressure (BP) in patients with hypertension (HT) who were resistant to antihypertensive agents. A specific device (catheter and generator) that allow for renal denervation has been commercially available in France since 2011. It makes it possible to perform renal denervation using a low-energy radiofrequency current, the thermal effect of which will reach by dissipation the adventitia of the renal artery in which the sympathetic nerve fibres are located that will then be destroyed.

The rules of good use of this medical device have yet to be published in the recommendations of knowledgeable societies. Several knowledgeable French societies bringing together specialists in HT, cardiology and interventional radiology have wanted to provide guideposts and rules of good uses for clinical and interventional physicians concerning the indications, the procedure and the follow-up of renal denervation for the treatment of HT.

This document, which was written by expert consensus, may be adapted depending on changes in new devices made available to medical professionals, but also clinical studies, the results of which will become known in the months and years to come.

Resistant hypertension: current diagnosis and treatment

HT is the most common CV risk factor and chronic disease in France, with more than 12 million patients treated with antihypertensive agents. Despite the means implemented to treat HT, the control of HT in treated hypertensive patients remains insufficient, as HT control defined as BP less than 140 and 90 mmHg in consultation is only achieved in 50% of treated patients [1]. When a treated hypertensive patient does not reach the BP objective, he or she is described as having uncontrolled HT. In this situation, the treatment should include:

- an evaluation of the correct compliance with the prescribed treatments;
- a reinforcement of advice and non-medicinal monitoring measures with restriction of sodium chloride intake via a reduction in the amount of foods that are rich in "hidden salt" (bread, cheese, preserved meats),

follow-up of nutritional measures that make it possible to lose 4 to 5 kg, a decrease in consumption of alcoholic beverages;

- a rationalisation of the use of antihypertensive agents with the optimisation of the choice of pharmacological groups. If the efficacy of monotherapy is insufficient, bitherapy should be initiated, followed by tritherapy, which should include: a renin-angiotensin system blocker (ARA2 or ACE inhibitor or direct renin inhibitor), a calcium-channel blocker and a thiazide diuretic.

When a treated hypertensive patient has not reached the BP objective despite the prescription of tritherapy including medicinal products prescribed at the maximum tolerated dosage and including a diuretic, he or she is described as having "resistant HT", according to the definition used in the recommendations [2]. In order to confirm the diagnostic of resistant HT, treatment should include:

- an ambulatory measurement of BP (AMBP) or automatic BP measurement (ABPM) in order to check the permanence of the lack of BP control, with a BP decision threshold of 135 and/or 85 mmHg for the daytime mean of AMBP or the mean ABPM;
- laboratory and/or radiology tests in order to screen for secondary HT [2]. The most common causes of secondary HT are as follows: nephropathy, sleep apnoea, adrenal causes and renal artery stenosis.

Resistant HT, when confirmed, requires specialised treatment as per the recommendations [2]. Treatment should include:

- reinforcement of treatment (increase of the dose of antihypertensive agents up to the maximum tolerated dose, choice of another diuretic);
- the addition of an aldosterone antagonist (spironolactone);
- the addition of other pharmacological groups (alpha blockers, central antihypertensive agents, direct vasodilatory agents);
- use of fixed combinations of antihypertensive agents;
- use of AMBP to monitor the efficacy of the treatments;
- normalisation of salt intake.

The incidence of resistant HT in populations of hypertensive patients is very variable and depends on several parameters: studied population, etiological assessment,

presence of severe renal insufficiency, specialized treatment. The data obtained on a general population living in the USA between 2003 and 2008 indicate that resistant HT is observed in approximately 9% of treated HT patients [3]. Patients with resistant HT are exposed in a premature manner to target organ damage and to the early onset of cardiovascular (CV) complications leading to an increase in morbidity and mortality. It has been shown that the CV prognosis is directly related to the BP level, which justifies the treatment of resistant HT in order to obtain BP control [4]. When resistant HT is not controlled despite specialized treatment, an improvement in BP control has recently been made possible through the use of interventional techniques that act on the nervous regulation of BP. Vagal stimulation via baroreflex activation and renal denervation by catheterization of the renal arteries are two methods that have recently been developed [5,6]. Their use in the treatment of resistant HT is not explicit in the recommendations. The objective of the creation of an expert consensus on the use of renal denervation in HT is to define the indications of the method, to help perform the technique properly and to organize patient follow-up.

Physiopathological mechanisms and prerequisites for the use of renal denervation in hypertension

Role of the autonomic nervous system in the physiopathology of hypertension

The autonomic nervous system participates in the physiopathology of HT via an activation of the sympathetic system, the central or peripheral origin of which depends on reflexes (baro, chemical or mechanical reflexes) or humoral substances [7]. The involvement of the renal sympathetic nervous system in the regulation of BP is complex, due to the role played by the efferent sympathetic tone destined for the renal parenchyma and by the afferent sympathetic tone from the kidneys. Therefore, the renal sympathetic system, which participates in the regulation of BP, plays a role in the initiation and persistence of HT.

Role of the renal sympathetic nervous system on blood pressure

In the kidneys, efferent sympathetic innervation is destined for the vascular system, renal tubules and juxtaglomerular apparatus. Stimulation of the sympathetic system participates in vascular constriction via two mechanisms: the stimulation of the beta-adrenergic receptors of the juxtaglomerular apparatus leading to the stimulation of the renin-angiotensin system and the increase in volume; and the stimulation of vascular alpha-adrenergic receptors leading to direct vascular constriction. The reduction in efferent renal sympathetic tone activity via experimental methods of renal denervation has reduced BP in different animal models [8]. Renal sympathetic afferences participate in the modulation of the activity of the central sympathetic system. They become involved via stimuli detected by the

mechanical and chemical receptors located in the kidneys that are sensitive to variations in electrolyte concentrations, plasma osmolality and hypoxia caused by renal ischaemia [9]. The interruption of renal sympathetic afferences obtained via nephrectomy is accompanied by a reduction in the total sympathetic activity and a decrease in BP [10]. Renal denervation by a surgical method is accompanied by a reduction in peripheral and central sympathetic activity and a reduction in the release of renin without a change in the glomerular filtration rate. The surgical denervation techniques (splanchectomy, sympathectomy) are no longer used, as serious complications (orthostatic hypotension, impotence, sphincter incontinence) were observed after these procedures [11].

Principles of renal denervation by radiofrequency applied via the endovascular route

Renal denervation via radiofrequency applied via the endovascular route is a method that destroys peripheral nerve fibres that surround the trunk of the renal arteries [6]. It causes a reduction in sympathetic tone of renal origin with a decrease in BP.

Clinical studies on renal denervation by radiofrequency in the treatment of hypertension

The SIMPLICITY 1 and 2 studies: inclusion of subjects with resistant hypertension without renal insufficiency with compatible renal arterial anatomy

Two clinical studies evaluated the effects of renal denervation via radiofrequency in patients with resistant HT [12,13]. SIMPLICITY 1 ($n=50$) is the pilot feasibility study [13], and SIMPLICITY 2 ($n=106$ randomised patients for 190 pre-selected patients) [12] is the randomized study carried out in patients with resistant HT evaluating the efficacy of renal denervation on BP compared to a group treated with medicinal products. The inclusion criteria were very close in both protocols. The included patients corresponded to the definitions of treated and uncontrolled HT:

- systolic BP in consultation (mean of three measurements) greater than 160 mmHg or greater than 150 mmHg in patients with diabetes;
- treatment with at least three antihypertensive agents that should include a diuretic (SIMPLICITY 1);
- persistence of uncontrolled HT after monitoring for 15 days;
- good compliance with treatments evaluated at the patient interview;
- glomerular filtration rate more than 45 mL/min/1.73 m².

The anatomy of the renal arteries was to be compatible with the endovascular denervation technique:

- a main renal artery on each side of at least 20 mm in length and 4 mm in diameter;

Table 1 Effects of renal denervation on blood pressure in SIMPLICITY 1 and 2.

	Inclusion	Change in BP at 1 month	Change in BP at 3 months	Change in BP at 6 months	Change in BP at 9 months	Change in BP at 12 months	Change in BP at 24 months
Pilot study (SIMPLICITY 1)							
Consultation BP	177/101 (n = 45)	−14/−10 (n = 41)	−21/−10 (n = 39)	−22/−11 (n = 26)	−24/−11 (n = 20)	−27/−17 (n = 9)	ND
ABPM (n = 12) Mean of SBP over 24 hours	ND	ND	ND	ND	ND	−11 mm Hg (95% CI: 7) (n = 9)	ND
Randomised study (SIMPLICITY 2)							
Consultation blood pressure in the denervation group (n = 52)	178/97		−20/−6 (versus control, n = 46)	−33/−11 (versus control, n = 46)			ND
Automatic measurement				−22/−12 (versus control, n = 32)			ND
AMBP over 24 h				−8/−6 (versus control, n = 20)			ND
Follow-up of the cohort at 24 months (n = 18, patients in SIMPLICITY 1 and other similar patients)							

- absence of renal artery stenosis or history of revascularisation procedures;
- denervation could not be carried out due to anatomical abnormalities in 10 to 20% of pre-selected patients in the SIMPLICITY studies.

Effects of renal denervation on blood pressure

The effects on BP were evaluated at 6 months following renal denervation [12–14] (Table 1):

- in 86 patients of a group of 153 patients treated on an open-label basis, the decrease in systolic BP (SBP)/diastolic BP (DBP) was of 25/11 mmHg, respectively, clinically measured;
- in 49 patients treated with renal denervation in SIMPLICITY 2, the decrease in SBP/DBP was of 32/12 mmHg, respectively, clinically measured. By comparison, in 51 patients in the control group treated with medicinal products, the decrease in SBP/DBP was of 1/0 mmHg, respectively;
- the percentage of patients treated with renal denervation with a SBP less than 140 mmHg was 39%;
- the percentage of responding patients (decrease in SBP more than or equal to 10 mmHg) was 85% in patients

treated with renal denervation and 35% in the group treated with medicinal products;

- in the 20 patients treated with renal denervation in SIMPLICITY 2, an evaluation of BP by ABPM was performed before and after 6 months of follow-up. The decrease in SBP/DBP was of 11/7 mmHg, respectively, in the denervated group;
- 10% of patients had no BP benefit from renal denervation;
- the decrease in BP was not immediate after the procedure. The maximum effect was observed after 3 months of follow-up;
- antihypertensive treatments were not decreased in most subjects and total treatment discontinuation was not carried out in any patients;
- renal denervation was not accompanied by orthostatic hypotension.

Effects of renal denervation on the activity of the sympathetic nervous system

A reduction in renal and overall sympathetic activity was observed in ten subjects in the SIMPLICITY 2 study, 30 days after renal denervation.

Complications observed from renal denervation applied via the endovascular route

During the renal denervation procedure, intense pain is felt by the patient and the application of the technique requires suitable analgesia carried out by an anaesthetist. In the SIMPLICITY 2 study, in seven patients out of 52, it was necessary to use atropine during the procedure due to the onset of bradycardia. In the SIMPLICITY 1 study, of the 45 patients followed-up, one case of renal artery dissection was observed as well as one case of pseudo-aneurism to the point of femoral puncture.

In the SIMPLICITY 2 study, of the 52 patients who had the initial procedure, the following were observed: one case of femoral pseudo-aneurism, one case of hypotension requiring a reduction in the number of antihypertensive agents prescribed, one case of urinary tract infection, once case of post-procedure paresthesia and one case of lumbago that resolved after one month. During the 24-month monitoring period of a cohort including 153 patients treated on an open-label basis [14], one renal artery dissection and three femoral pseudo-aneurisms were observed. Follow-up at 6 months of the anatomy of the renal arteries (mainly by Doppler) in 43 evaluable patients treated in the randomised study and 81 patients treated on an open-label basis showed no vascular abnormalities in the treated areas. One case of renal artery stenosis that progressed after 6 months of follow-up and that required angioplasty was reported. Kidney function in 49 patients in the SIMPLICITY 2 study with an initial GFR more than 45 mL/min remained stable at 6 months following denervation. No longer-term data is available.

Two patients from the cohort monitored for 24 months died (one myocardial infarction and one sudden death) during the follow-up period. These deaths were not attributed to the denervation procedure. In all, 3.5% of patients included in these studies had an early adverse event. The low number of patients included in these studies does not currently make it possible to rule out a rare and serious risk with a frequency of less than 5% in the short, medium and long-term and currently justifies indefinite clinical and radiology monitoring of patients who have had renal arterial denervation.

Experience with renal denervation in the treatment of hypertension is still limited

The limits concerning the results of published studies are as follows:

- the numbers of patients included in the studies are very low (202 patients whose results were published);
- the duration of follow-up is short, which does not make it possible to evaluate the risk of rare and/or long-term adverse effects;
- the patients included did not all benefit from optimal anti-hypertensive treatment, as 5 to 10% did not receive a diuretic and less than 20% received an anti-aldosterone agent;
- the patients included in the studies did not all benefit from APBM/AMBP, which is the way to screen for uncontrolled HT caused by the white-coat effect;
- the results on BP beyond 24 months are not known;
- the study of the activation of the sympathetic system, which is based on the use of complex experimental techniques, cannot be performed in clinical practice;
- no criteria make it possible to predict the intensity of the decrease in BP induced by renal denervation via the endovascular route;
- no markers are currently available to indicate an effect on the renal sympathetic system during and after the procedure.

The analysis of the data in the literature indicate that new studies need to be conducted in order to answer the questions that have yet to be resolved concerning renal denervation for the treatment of HT:

- quantification of the decrease in BP using ABPM/AMBP;
- criteria predictive of the efficacy of renal denervation via the endovascular route on BP;
- criteria of the efficacy of renal denervation during the procedure;
- BP efficacy and anatomical change in renal arteries after long-term follow-up;
- medico-economic evaluation of renal denervation via the endovascular route as a method of treatment for resistant HT.

Indications of renal denervation via the endovascular route in the treatment of hypertension in 2012

In 2012, the expert consensus limits the indication of the technique of renal denervation to patients who have essential uncontrolled HT receiving four or more treatments ([Appendix A](#)):

- with a treatment including at least one diuretic;
- spironolactone at a dose of 25 mg that has been ineffective;
- with at least SBP more than 160 mmHg and/or DBP more than 100 mmHg in consultation;
- and confirmation of SBP more than 135 mmHg and DBP more than 85 mmHg via ABPM or by AMBP (daytime period);
- with a glomerular filtration rate more than 45 mL/min/1.73 m²;
- with renal artery anatomy that is compatible with the procedure;
- with the presence of two functioning kidneys measuring more than or equal to 90 mm;
- who have had, before the procedure, an exploration of the renal arteries via a radiology imaging technique (angio-CT scan, angio-MRI or arteriography);
- with no history of angioplasty/stent in the target renal arteries;

- with an approach route compatible with the procedure;
- with an indication established after multi-disciplinary discussion including a physician who has practice and skill in the treatment of patients with HT.

The renal denervation technique cannot be used in patients with HT and:

- renal artery stenosis more than 30%;
- renal artery fibro-muscular dysplasia;
- who are under 18 years of age;
- who are currently pregnant.

Recommended procedure for renal denervation via the endovascular route in the treatment of hypertension

The expert consensus brought together in 2011 recommended the following organisation and procedure for the application of renal denervation technique via the endovascular route.

Technical facilities

Suitable technical facilities should include an angiography room that allows for the following:

- a good visualisation of the two nephrogrammes in overall angiography;
- high quality scopy. Use of an OR-mobile C-arm is not suitable for this procedure;
- optimal radioprotection conditions.
- The images should include:
- imaging of the kidneys, right and left renal arteries before and after the renal denervation (overall aortography with delayed sequences that ensure the absence of renal embolic complications or dissection);
- images from the beginning and the end of the procedure as well as the position of the catheter at the different removal sites must be archived in a computer system.

The angiography room must be located in an environment that makes it possible for an anaesthetist to perform sedation/analgesia.

Operator training

Renal denervation is a complex procedure that can have risks of arterial complications. Training is necessary for the first cases as well as learning how to use the specific material. Interventional radiologists/cardiologists should have carried out either:

- 15 renal arterial angioplasties \pm stent;
- or ten renal arterial angioplasties and 50 peripheral arterial angioplasties within the last 2 years;
- or have carried out renal angioplasties on a regular basis in the past 5 years (5/year) and regularly performed renal arterial catheterisation for embolisation regardless of the cause on a regular basis (10/year in the last 2 years).

Procedure for renal denervation by radiofrequency

The procedure requires the insertion via the renal intra-arterial route, as per the principles of arterial catheterisation, of a specific single-use catheter that allows for renal denervation. The denervation catheter approved for the treatment of the renal arteries is coupled with a generator of low-energy radiofrequency current, the thermal effect of which dissipates in the adventitia of the renal artery in which the afferent and efferent sympathetic nerve fibres are located and destroys them.

The method should follow a standardised procedure: correct positioning confirmed by impedancemetry, delivery of radiofrequency current, cooling of the extremity of the catheter by blood flow, impulse sequence for a duration of 2 minutes, the power delivered by the catheter and the temperature collected in real time that conditions later impulses, withdrawal with a 60° to 90° rotation of the catheter per 5 mm interval starting from the initial removal zone close to the renal hilum, the performance of four to six deliveries of radiofrequency current, circumferential and focal denervation following a helicoidal pattern. The renal denervation procedure can be performed:

- if there is at least one renal artery on each side, the diameter of which is greater than 4 mm;
- if the length of the main trunk of the renal artery is at least 20 mm, making it possible to deliver at least four shots;
- in one artery only of each kidney.

During the procedure, the following minimal actions should be undertaken:

- monitoring of vital signs (heart rate, BP, etc.);
- anti-coagulation with heparin at an effective dose;
- nitrate derivatives by injection in the renal artery before the procedure;
- checking the programming of a cardiac stimulator or an automatic defibrillator after the procedure if renal denervation is performed in a patient with this type of device.

In case of vascular complications during the procedure, it is necessary to:

- have specific material available in the catheterisation/angiography room that makes it possible to urgently implant a stent of a suitable calibre (6 mm) in the renal artery in case of dissection;
- interrupt the procedure in case of a vascular complication occurring in one of the arteries;
- report the complication to the materiovigilance centre of the site.

Follow-up of patients who have had renal denervation via the endovascular route for the treatment of hypertension

The recommendations for the follow-up of patients who have had renal denervation are:

- In the short-term, the patient should be monitored as per the monitoring rules of a renal/peripheral arterial angioplasty. Monitoring for 1 hour is desirable in the post-procedure monitoring room before returning to the hospital room and a hospital stay of 24 h.
- Monitoring of BP (ABPM/AMBP): after 6 months, after 12 months, after 24 months, after 36 of the renal denervation procedure.
- Monitoring of the anatomy of the renal arteries: angio-CT scan (optimal analysis of the anatomy of the renal arteries) after 12 months and after 36 months of the renal denervation procedure.
- Usual monitoring of kidney function within the framework of HT, including the following in particular: serum creatinine levels, proteinuria (if initial proteinuria) after 6 months, after 12 months, after 24 months, after 36 months of the renal denervation procedure.
- The antihypertensive treatment should not be interrupted immediately after the renal denervation procedure, as the effect on the decrease in BP is delayed and reaches its maximum effect after 3 months according to the SIMPLICITY studies.
- Changes in the antihypertensive treatment should be carried out by the physician treating the patient for HT. The expert consensus mandates the inclusion in the SFHTA/SFC/SFR/GACI register for "renal denervation in HT" of all patients in France who have had the renal denervation technique, either within the framework of a studies and/or protocols or within the framework of clinical treatment outside of a protocol.

Disclosure of interest

Atul Pathak, Xavier Girerd, Hakim Benamer, Jean-Michel Halimi and Pierre Lantelme declare that they have no conflicts of interest concerning this article.

Michel Azizi declares: investigator in the study SIMPLICITY HTN2 (Ardian Inc.), consulting activity for Vessix Vascular.

Thierry Lefevre declares: consulting activity for Medtronic.

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Appendix A. Information leaflet for patients having renal denervation via the endovascular route with radiofrequency

Renal denervation via the endovascular route for the treatment of hypertension

Your BP remains too high despite the use of several antihypertensive medicines. We are offering you a new technique

called renal denervation that can improve the efficacy of the HT treatments.

How does it work?

The principle of renal denervation is to interrupt the activity of the sympathetic nerves that surround the arteries of the kidneys and that participate in HT. The method uses heat emitted by a miniature device positioned at the end of a catheter that is inserted in the arteries that lead to the kidneys (renal arteries). The heat is generated by a system using a radiofrequency current specially developed in a medical device with a technical evaluation (CE label) making it possible to use it in the European Union and in France.

At the beginning of the year 2012, this system had been used in a few hundred patients in the world. The results of clinical studies concluded that renal denervation can be used to reduce BP in patients with uncontrolled HT despite medicinal treatment, and that the risks related to this method are minimal.

What happens during the procedure?

The procedure will be performed in a department that makes it possible to carry out interventional radiology examinations. To avoid pain associated with this procedure, you will be given medicines that will make you sleepy and will relax you. In some cases, general anaesthesia may be given.

The procedure will begin with arteriography that will visualise the renal arteries. After local anaesthesia, a needle will be inserted into the groin making it possible to introduce a tube (catheter) with a small diameter (about 1.7 mm) into the femoral artery. The catheter will then be inserted into the main renal arteries under radiological monitoring and it will be injected with a contrast medium that will make it possible to see the renal arteries.

Once the renal arteries have been located, the specific catheter that carries the radiofrequency system will be positioned in the renal artery. The treatment will be applied via 2 minutes sequence for four to six sequences in each renal artery. After having treated each renal artery (left and right), the material will be withdrawn.

At the end of the examination, prolonged compression of the groin will be performed to avoid bruising at the puncture point. A compressive bandage will be applied. You will then have to remain lying down for 24 hours under medical monitoring. You will be allowed to get up from your bed and walk starting from the 24th hour after the procedure. You will then be able to go home.

Follow-up visits

You will be seen again regularly in consultation for monitoring visits at 3, 6 12 and 24 months after the procedure to monitor your BP and to adjust the number of your antihypertensive medicines. It is recommended that a scan examination of the renal arteries be carried out after 12 months and after 36 months to monitor the proper functioning of the renal arteries.

What is the expected benefit?

The expected benefit of the renal denervation technique is an improvement in the efficacy of HT treatments on BP. Before the procedure, it is not possible to predict the extent of the decrease in BP that will be obtained through renal denervation. According to the published studies, in most patients treated with renal denervation, a decrease in BP is observed that is at its maximum 3 months after the procedure. This decrease in BP makes it possible to decrease the number of medicines necessary to treat your HT. However, it is rarely possible to discontinue all the medicines.

What are the risks?

The main risks related to the renal denervation procedure are similar to those run during any diagnostic or therapeutic investigation (for example, during dilation of an artery with or without the insertion of an endoprosthesis) involving arterial catheterization. With regard to safety, two studies have investigated the short and medium-term risk of the technique (6 to 12 months). The safety data published to date concern the 202 patients who have been treated with the procedure.

The frequency of the onset of complications remains very low, particularly for the most serious complications (one reported case of dissection of a renal artery treated with a stent). Pain and bruising at the arterial puncture point in the groin are the local complications for which the frequency is highest (1 to 10%). These data are reassuring. Checking the condition of the renal arteries a certain period of time afterwards (6 to 12 months) showed no kidney function abnormalities (kidney function stable). List of complications that may occur during renal denervation via the endovascular route:

- Arterio-venous fistula (abnormal communication between a vein and an artery).
- Local infection.
- External bleeding (at the puncture site).

Complications related to the renal denervation: frequency of less than 1%:

- Abdominal pain during the procedure that is attenuated or avoided by the use of analgesics and/or anaesthetics. These medicines can themselves decrease BP and/or breathing rate, and sometimes results in nauseous sensations or even vomiting and constipation.
- Damage to the arterial wall related to radiofrequencies and/or ultrasounds (theoretical risk).
- Hypotension, particularly when standing (but the observed drop in BP occurs gradually over a period of weeks).
- Haematuria (blood in the urine).
- Other risks that are not currently known (like with any new treatment).
- Like any new procedure, other risks that are not currently known cannot be ruled out. Their incidence is very low.

Date:

I have received the information concerning the renal denervation procedure proposed by
 Doctor..... and he or she
 answered my additional questions during my
 interview with him or her.

Last name:

First name:

Signature

General complications related to arteriography: frequency of less than 1%:

- Nausea or vomiting
- Complications related to the use of contrast media such as allergic reactions or renal insufficiency related to the contrast medium.
- Heart rhythm disturbances, for example, heart rate that is too slow
- HT - BP that is too low
- HT - BP that is too high
- Intra-peritoneal bleeding - (bleeding in the intra-abdominal area)
- Fever after the procedure that may or may not be related to an infection
- Death

Local complications related to arteriography: frequency of less than 1%:

- Arterial embolism (clot that can temporarily or permanently affect the functioning of some organs).
- Vascular complications (requiring surgery).
- Perforation or dissection of a renal artery (requiring the insertion of an arterial stent).
- Pain at the puncture site.
- Bruise, pseudo-aneurism (dilation of the arterial wall).

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